510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:
k043245

B. Purpose for Submission:
New device

C. Measurand:
Glucose

D. Type of Test:
Quantitative; electrochemical biosensor

E. Applicant:
EPS Bio Technology Corporation

F. Proprietary and Established Names:
Easy Pain Supreme Self Monitoring Glucose Test System

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1345, Glucose Test System
   21 CFR 862.1660, Quality control material (assayed and unassayed).
2. Classification:
   Class II
   Class I, reserved

3. Product code:
   NBW, System Test, Blood Glucose, Over the Counter
   CGA, Glucose Oxidase, Glucose
   JJX, Single (Specified) Analyte Controls (Assayed and Unassayed)

4. Panel:
   Chemistry 75

H. Intended Use:

1. Intended use(s):
   see Indications for Use below

2. Indication(s) for use:
   The Easy pain Supreme Self Monitoring Blood Glucose Test System is used by individuals with diabetes. It is for the quantitative measurement of glucose levels in fresh capillary whole blood, as an aid in monitoring the effectiveness of

diabetes management in the home and in clinical settings.

3. Special conditions for use statement(s):
   N/A
4. Special instrument requirements:
   N/A

I. Device Description:

The Easy Pain Supreme Self Monitoring Blood Glucose System is comprised of the Easy Pain Supreme Blood Glucose Meter, Easy pain Supreme Glucose Test Strips, Auto Lancet, Check strip, code card and control solutions.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   MediSense, Inc. Precision QID Blood Glucose Testing System

2. Predicate 510(k) number(s):
   k971812, k962295

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Detection method	Amperometry: current is generated by oxidation of reduced mediator	Amperometry
Enzyme	Glucose oxidase (Aspergillus niger)	Glucose oxidase (Aspergillus niger)
Mediator	Potassium ferricyanide	Potassium ferricyanide
Electrode	Carbon electrode	Carbon electrode

Differences		
Item	Device	Predicate
Test range	40-600 mg/dL	20-600 mg/dL
Hematocrit range	30-55%	20-70%
Test time	25 seconds	20 seconds
Sample volume	$\geq$ 2.0 uL	$\geq$3.5 uL
Temperature range	10-40^{0}C	18-30^{0}C
Humidity range	R.H. $\leq$ 90%	R.H. 10-90%
Coding	Code card	Calibrator
Memory capability	100 tests with date and time	N/A
Power	1.5V (AAA) batteries	Non-replaceable cell 3.0V/DC
Battery life	Approx. 1000 tests	Approx. 4000 tests
Size L x W x H (cm)	7.5 x 5.4 x 1.9	9.7 x 4.8 x 1.45
Weight	50g (without batteries)	39.35g

K. Standard/Guidance Document Referenced (if applicable):

1. CLSI EP5-A, Precision Performance of Clinical Chemistry Devices
2. CLSI EP6-P, Evaluation of the Linearity of Quantitative Analytical Methods; Proposed Guideline
3. CLSI EP7-P, Interference Testing in Clinical Chemistry; Proposed Guideline
4. ISO 15197:2003, In Vitro Diagnostic Test Systems – Requirements for Blood Glucose Monitoring Test Systems for Self Managing Diabetes Mellitus
5. IEC 60601-1-2, Medical Electrical Equipment – Part 1: General Requirement for Safety; Electromagnetic Compatibility – requirements and Tests
6. IEC 61010-1, Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 1: General Requirements
7. IEC 60601-2-101, Safety Requirements For Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment
8. IEC 60068-2-64, Environmental Testing- Part 2: Test Methods- Test Fh: Vibration, Broad-band Random (Digital Control) and Guidance
9. IEC 61326 (2002-02) – (for reference), Electrical Equipment for Measurement Control, and Laboratory Use – EMC Requirements
10. ISO 14971:2000, Medical Devices – Application of Risk Management to Medical Devices
11. ISO 15223:2000, Medical Devices – Symbols to be Used With Medical Device Labels, Labeling, and Information to be Supplied
12. EN 376:2002, Information Supplied by the Manufacturer With In Vitro Diagnostic Reagents for Self Testing
13. ISO 10993-1, Biological Evaluation of Medical Devices – Part 1:Evaluation and Testing
14. EN 13640:2002 Stability Testing of In Vitro Diagnostic Reagents

L. Test Principle:

The Easy Pain Supreme Self Monitoring Blood Glucose System employs a disposable dry reagent strip technology, based on the glucose oxidase method for glucose determination. Each test strip features an electrode containing the enzyme glucose oxidase (Aspergillus niger). A blood sample is applied to the blood collection area at the tip of the strip and is automatically drawn into the reaction zone, where the glucose oxidase catalyzes the oxidation of glucose to produce gluconic acid. During the reaction, a mediator transfers electrons to the electrode surface and generates a current. The amount of the current is proportional to the amount of glucose present in the blood sample. The glucose concentration is displayed on the meter screen after 25 seconds.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
      Within-run – Testing was conducted by taking 4 mL of blood that was treated with heparin through a vacuum tube. Glucose was added to the 4 mL of blood

to generate 5 different levels of glucose concentration for the test. Each of the samples was measured 5 times. The glucose concentration ranges were: 40-50 mg/dL, 51-110 mg/dL, 111-150 mg/dL, 151-250 mg/dL, and 251-400 mg/dL.

Range (mg/dL)	n	mean (mg/dL)	SD (mg/dL)	CV (%)
40-50	200	43	2.4	4.3
51-110	200	95	5.3	3.5
111-150	200	144	8.0	3.3
151-250	200	246	13.7	3.1
251-400	200	398	22.1	3.3

Day to day - Three control solutions of Low, Normal and High were prepared. Each of the controls was measured twice a day, once in the morning and once in the afternoon for a month.

Control	n	mean (mg/dL)	SD (mg/dL)	CV (%)
Low	400	56	3.10	5.6
Normal	400	129	4.49	3.5
High	400	388	10.21	2.6

b. *Linearity/assay reportable range:*
A blood sample of 25 mL was taken, treated with heparin vacuum tube, to be set for a day. Testing was performed using whole blood supplemented with B-D-glucose to provide samples at seven different blood glucose levels (40-50 mg/dL, 51-80 mg/dL, 81-120 mg/dL, 121-200 mg/dL, 201-300 mg/dL, 301-400 mg/dL, and 400-600 mg/dL). A total of 210 tests were performed using 5 meters among the seven glucose ranges per each strip lot. The linear regression was as follows:

$$y = 0.9589x + 6.1617,\ r^2 = 0.9958,\ Syx = 10.14,\ n = 630$$

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
N/A

d. *Detection limit:*
Data was provided to support a reportable range of 40-600 mg/dL.

e. *Analytical specificity:*
Interference testing was conducted to determine the effect of select endogenous and exogenous substances. A series of test samples, systematically varying in the concentration of the interferents, was prepared by making quantitative, volumetric mixtures of two pools: one at the highest concentration to be tested and the other at the lowest. The substances and concentrations of the interferents are recommended in CLSI EP7-P. Interference from dopamine and L-dopa was observed when the recommended concentration of these drugs was reached in the blood.

Interference was also observed in higher than therapeutic dosages of acetaminophen, gentisic acid, and methyldopa.

f. Assay cut-off:
N/A

2. Comparison studies:
   a. Method comparison with predicate device:
   Two hundred two people with diabetes performed a finger stick using the Easy Pain Supreme system. A healthcare professional then performed the test on the Easy pain Supreme and the YSI. The range of glucose values for these samples was 33-514 mg/dL. The linear regressions were as follows:

   Patient vs YSI $y = 0.967x + 11.98$, $r = 0.972$

   Healthcare professional vs YSI $y = 1.007x + 5.04$, $r = 0.957$

   b. Matrix comparison:
   N/A

3. Clinical studies:
   a. Clinical Sensitivity:
   N/A

   b. Clinical specificity:
   N/A

   c. Other clinical supportive data (when a. and b. are not applicable):
   see section 2.a.

4. Clinical cut-off:
   N/A

5. Expected values/Reference range:
   Expected blood glucose levels for people without diabetes (refereced from Joslin Diabetes Manual):

Time	Range (mg/dL)	Range (mmol/L)
before breakfast	70-105	3.9-5.8
before lunch or dinner	70-110	3.9-6.1
one hour after meals	less than 160	less than 8.9
two hours after meals	less than 120	less than 6.7
between 2 and 4 AM	greater than 70	greater than 3.9

N. Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.